



Medtronic

APR 30 2014

K132617 510(k) Summary
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Traditional 510(k) Summary

Submitter: Medtronic Vascular
37A Cherry Hill Drive
Danvers, MA 01923,
USA

Contact Person: Nisarg Shah
Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, MA 01923
USA
Phone: (978)-739-6632
Fax: (978)-750-8204
Email: nisarg.g.shah@medtronic.com

Date Prepared: April 23, 2014

Trade Name: Input® PS Introducer

Common Name: Catheter Introducer

Classification Name: Catheter introducer
Class II per 21 CFR §870.1340, Product Code DYB.

Predicate Device: USCI Input™ Introducer [K940092 clearance received on August 10th, 1995]; referred to as Input PS Introducer in this premarket notification for identification purposes.

Device Description: The Medtronic Vascular Input® PS Introducer is comprised of a sheath, a locking dilator, a Needle and a guide wire. This set may also contain an introducer obturator which must be left in dwelling post PTCA. Individual components within the Input® PS Introducer set are described below:

1. **Input PS Dilator:** The function of a dilator is to dilate the artery or vein to provide a less traumatic entry of the introducer sheath to a vasculature. The dilator is usually placed inside the lumen of the introducer sheath during sheath insertion.



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2. **GuideWire:** The guidewire is inserted through the needle into the vessel and provides a platform over which the dilator and introducer sheath can be advanced. The guidewire is available with a maximum outer diameter of 0.038" Double Distal "J" guidewire approximately 15cm in length.
3. **Input PS Introducer Sheath:** The Input PS Introducer sheath allows for placement of various devices into the vasculature. The sheath shaft is coated with hydrophilic coating to improve ease of insertion. The Input Introducer sheath is available in two different lengths: 11cm sheath and 23cm sheath. The 11cm sheath is available in five different diameters measured in French size (5F, 6F, 7F, 8F and 9F). The 23cm sheath is available in four different diameters measured in French size (6F, 7F, 8F and 9F).
4. **Needle:** The needle provided with the Percutaneous Catheter Introducer Set is a standard puncture needle. The needle is used to puncture the vessel to provide route into the vessel for the guidewire.
5. **Obturator:** The Medtronic Input Introducer Obturator is inserted into an introducer sheath to provide support and help maintain sheath patency when placement of an intravascular catheter is delayed or removed.

**Statement of
Intended Use:**

The Medtronic Vascular Input PS Introducer is a percutaneous introducer used to facilitate placing a catheter through the skin into a vein or artery. Percutaneous introducers are recommended for initial percutaneous introduction or the exchange of intravascular devices.

**Summary of
Technological
Characteristics:**

The Medtronic Vascular Input PS Introducer sheath allows for placement of various devices into the vasculature. The Input PS Introducer sheath assembly involves following feature:

- i. Shaft (with hydrophilic coating)
- ii. Hub



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- iii. Strain relief
- iv. Hemostatic valve
- v. Sidearm tubing with a stop-cock.

Summary of Non-clinical Data:

The device performance qualification and the biocompatibility testing for the material modification was conducted in accordance with the relevant recommendations from the relevant FDA guidance to demonstrate that the modified Input PS Introducer sheath have met the acceptance criteria and performed similar to the predicate device:

Performance Qualification/ Bench Testing: Bench testing was performed specific to the material modification to the Input PS Introducer sheath. The following verification tests were performed to demonstrate the substantial equivalence of the modified Input PS Introducer Sheath to the predicate device:

- i. Visual Inspections
- ii. Coating length
- iii. Lubricity
- iv. Coating Durability
- v. Introducer Insertability
- vi. Particulate evaluation

Biocompatibility Testing: Pursuant to the ISO 10993-1: 2009- *Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process*; the biocompatibility testing for the modified Input PS Introducers was completed.

No new safety or effectiveness concerns were raised during the testing on the modified device. The performance qualification testing along with biocompatibility testing demonstrated that the modified Input PS Introducer sheath is safe, effective and substantially equivalent to the predicate device.

Summary of Clinical Data:

No clinical investigation has been performed on the modified device.



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**Conclusion from
Data:**

Medtronic Vascular has demonstrated that the modified Input PS Introducers are substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 30, 2014

Medtronic, Inc.
% Nisarg Shah
Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K132617
Trade/Device Name: Medtronic Input® PS Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Percutaneous Catheter Introducer
Regulatory Class: II
Product Code: DYB
Dated: February 27, 2014
Received: March 4, 2014

Dear Mr. Shah,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132617

Device Name: Medtronic Vascular Input® PS Introducer

Indications for Use:

A percutaneous introducer is used to facilitate placing a catheter through the skin into a vein or artery. Percutaneous introducers are recommended for initial percutaneous introduction or the exchange of intravascular devices.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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